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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/142,557 09/11/98 PILARSKI

L P-1459(O)

HM22/0130

HUGHES ETIGSON
175 COMMERCE VALLEY DRIVE WEST
SUITE 200
THORNHILL ON L3T 7P6
CANADA

AIR MAIL

EXAMINER

FONDA, K

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/142,557

Applicant(s)

Pilarski

Examiner

Charles Rones

Group Art Unit

2771

☒ Responsive to communication(s) filed on Nov 13, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 94 and 101-170 is/are pending in the application.

Of the above, claim(s) 94, 101, 102, 104, 105, 112, 113, 127-129, 137, 140, 142, and 145-170 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Any rejection or objection made in a prior Office action and not repeated herein is withdrawn in view of Applicant's arguments and/or amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

An initialed copy of Applicant's Information Disclosure Statement submitted 09-11-98 is enclosed. Although all references cited have been considered, Applicant is advised that a date for the reference identified as "Roitt, I., Brostoff, J., Male, D. **Immunology** 4:2.1" is required in order for the reference to be listed on the face of any patent which may issue from this application.

Claims 111, 114, 115, 136, 138, 143, and 144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. This represents a new ground of rejection for claim 111; the rejections of claims 114, 115, 136, 138, 143, and 144 are maintained from the Office action of 05-09-00.

Claim 111, by its preamble, is drawn to a method for administration of hyaluronic acid. Claim 111 is indefinite

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because it fails to recite any steps of such a method. The Examiner intended to make this rejection in the prior Office action, but through typographical error stated that claim 112 (not currently under prosecution) failed to recite method steps rather than claim 111. Technically this rejection is a new ground, so Applicant will note that this action has not been made final.

Claim 136 is indefinite because it lacks positive antecedent basis for "the form of hyaluronan" in lines 2 and 3. The Examiner also notes that because claim 136 depends from claim 133, sodium hyaluronate must be administered in claim 136. Applicant's arguments filed 11-13-00 have been fully considered but they are not persuasive. Applicant argues that claims from which claim 136 depends provide the needed antecedent basis. The Examiner does not agree. The offending language in claim 36 refers to "hyaluronan" rather than "hyaluronic acid" as is recited in claims 124, 125, 126, 131, and 132. Furthermore, insofar as claim 136 depends from claim 130, not even hyaluronic acid is mentioned. Applicant has not addressed the fact that claim 133, from which claim 136 depends, requires administration of sodium hyaluronate.

Claim 138 lacks positive antecedent basis for "the infusion", and is therefore indefinite. Applicant has not addressed this ground of rejection.

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Claims 103, 106-111, 114-126, 130-136, 138, 139, 141, 143, and 144 are again rejected, as set forth in the Office action of 05-09-00, under 35 U.S.C. 103(a) as being unpatentable over either HAMANN et al. (K) or HAN et al. (L), in view of FALK et al. (A).

Applicant's arguments filed 11-13-00 have been fully considered but they are not persuasive.

Applicant argues first that the Examiner has failed to show how all of the claimed elements are taught or suggested; Applicant focuses specifically on the *in vivo* requirement of the claims. As stated in the prior action, suggestions that the method can be used *in vivo* are provided by each of HAMANN (treatment of asthma suggested), HAN (clinical management of thrombocytopenias suggested), and FALK (administration of hyaluronic acid taught in the context of facilitation of administration of other drugs). Thus the *in vivo* aspect of the claims is suggested by the art as applied.

Applicant argues second that the Examiner has not provided motivation to combine. Applicant will note that HAMANN and HAN have been applied in the alternative rather than in combination, so no such motivation is needed as to HAMANN and HAN. Motivation to combine FALK's teaching as to administration of hyaluronic acid with either HAMANN or HAN is provided by HAMANN and HAN,

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which, respectively, suggest treatment of asthma and management of thrombocytopenias.

Applicant argues finally that there would have been no reasonable expectation of success. The Examiner does not agree. Based on the suggestions of HAMANN and HAN to use the method in a clinical setting, a person of ordinary skill would reasonably have expected the method to be successful. Absolute predictability is not required.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://pto-ebc.uspto.gov> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Mondays through Thursdays from 7:30-12:30. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner Gary Geist at (703) 308-1701. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'K. Kahler Fonda', is positioned above the typed name.

Kathleen Kahler Fonda, Ph.D.
Primary Examiner
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